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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,089	06/15/2006	Andreas Nandy	MERCK-3178	8804

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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08/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No. 10/583,089	Applicant(s) NANDY ET AL.	
	Examiner NORA M. ROONEY	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-17 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 14-17 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12, 13, 21-22, 24-25 is/are rejected.
- 7) ☒ Claim(s) 26-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 06/01/2010 is acknowledged.
2. Claims 1-10, 12-17, 21-24 and newly added claims 25-28 are pending.
3. Claims 1-9 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, and claim 23 is withdrawn from consideration as being directed to a non-elected species there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/19/2008.
4. In view of Applicant's amendments, the Examiner has extended the search to encompass the species of the polypeptides consisting of amino acids 23 to 518 of SEQ ID NO: 6; amino acids 23 to 518 of SEQ ID NO: 8; and amino acids 23 to 518 of SEQ ID NO: 10 of claim 26 in addition to the species of SEQ ID NO:4, SEQ ID NO:2, amino acids 23 to 518 of SEQ ID NO:2 and amino acids 23 to 520 of SEQ ID NO:4 which were previously examined. It is noted that, contrary to Applicant's assertion, the claims have not been examined for SEQ ID NOs 6,8 or 10.
5. Claims 10, 12-13, 21-22 and 24-28 are currently under examination as they read on the Sec c 4 polypeptide of SEQ ID NO:4, SEQ ID NO:2, amino acids 23 to 518 of SEQ ID NO:2 and amino acids 23 to 520 of SEQ ID NO:4 and the polypeptides consisting of amino acids 23

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to 518 of SEQ ID NO: 6; amino acids 23 to 518 of SEQ ID NO: 8; and amino acids 23 to 518 of SEQ ID NO: 10 and pharmaceutical compositions thereof.

6. The following new grounds of rejection are necessitated by the amendment filed on 06/01/2010.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10, 21-22 and 24 stand rejected and claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Gavrovic et al. (PTO-892 mailed on 11/28/2008; Reference V) as evidenced by the specification on page 4, lines 1 and 19-22 for the same reasons as set forth in the Office Action mailed on 03/29/2010.

Gavrovic et al. teaches the isolated Sec c 4 protein from *Secale cereale* having a molecular weight of about 55-60 kDa and a pI in the range of 9.2 to 9.7 (In particular, abstract).

The specification on page 4 teaches that Sec c 4 is the Group 4 allergen isolated from *Secale cereale* having the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO:4. The

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reference teaches the same isolated allergen from the same source, so the resulting allergen must necessarily have the sequence of SEQ ID NO:2 or SEQ ID NO:4.

Claims 10, 21-22 and 24-25 are included in this rejection because the recitations of: the sequence set forth in SEQ ID NO:2 or 4 or encoded by the sequence set forth in SEQ ID NO 1 or 3 in claim 10; and a polypeptide comprising SEQ ID NO: 2 or 4, a polypeptide comprising amino acids 23 to 518 of SEQ ID NO:2, a polypeptide comprising amino acids 23 to 520 of SEQ ID NO:4 or a polypeptide encoded by the sequence set forth in SEQ ID NO 1 or 3 in claim 24 add no patentable weight. Determining the sequence of the reference allergen is merely further characterization of a known compound. *Atlas Powder Co. V. IRECO*, 51 USPQ2d 1943 (Fed. Cir. 1999)"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Claim 21 is included in this rejection because the patentability of a product does not depend on its method of production. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Further, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 06/01/2010 have been fully considered, but are not found persuasive.

Applicant argues:

"At the outset, Applicant asserts that the fragment sequences consisting of the recited structural features fail outside Gavrovic's disclosure (i.e., calculated MW55 kDa for a[] fragments and calculated pI9.3 for the SEQ ID NO: 2 fragment). As such, the polypeptides recited in claim 25-27 are novel over what is taught by Gavrovic."

"With respect to the broader claims at issue, Applicants will not burden the record by reiterating the previous arguments. However, to ensure that the present reply is fully responsive to all the rejection(s) set forth in the present Office Action, Applicants' remarks filed February 3, 2010, along with the evidence/exhibits submitted therewith are incorporated by reference herein in their entirety."

It is the Examiner's position that the instant claims rejected are not directed to fragments. The Sec c 4 allergen of Gavrovic with a molecular weight of "about 55-60 kDa" and a pI "in range 9.2 to 9.7" is the same as SEQ ID NO:2 or SEQ ID NO:4, with molecular weights of 57.172 kDa and 57.171 kDa and pI values of 9.08 and 9.28, respectively. 57.172 kDa and 57.171 kDa are both "about 55-60 kDa" and pIs of 9.08 and 9.28 and are "in the range of 9.2 to 9.7." Since the office does not have a laboratory to test the reference sequences, it is applicant's burden to show that the reference molecules differ from the claimed sequences. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980). Recitations of sequences in the claims add no patentable weight. Determining the sequence of the reference allergen is merely further characterization of a known compound. *Atlas Powder Co. V. IRECO*, 51 USPQ2d 1943 (Fed. Cir. 1999). The same isolated Sec c 4 allergen was taught in the prior art of Gavrovic et al.

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Recitations of the sequence of SEQ ID NO:2 or SEQ ID NO:4 do not add patentability to the claims because it is only further characterization of a known compound.

Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 12-13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavrovic et al. (PTO-892 mailed on 11/28/2008; Reference V) in view of U.S. Patent 5,762,943 (PTO-892; Reference A) for the same reasons as set forth in the Office Action mailed on 03/29/2010.

"It is submitted that *any* holding of obviousness based on Gavorovic's generic disclosure of *Sec c 4* proteins is scientifically and legally misplaced. See Applicants' remarks and the exhibits filed with the reply of February 3, 2010. To this end, it is respectfully submitted that Gavorovic says nothing about the *Sec c4* allergens having the recited sequences and specific fragments thereof that are recited in claim 25. Withdrawal of the rejection is respectfully requested.

With respect to the other dependent claims at issue, Applicants will not burden the record with a discussion of same since they merely add to the non-obviousness of claims 24 and 25. However, Applicants reserve the right to provide rebuttals against the statements in the Office Action vis-a-vis the dependent claims, at a later date, if ever necessary."

It is the Examiner's position that the instant claims rejected are not directed to fragments.

It would have been obvious to one of ordinary skill in the art to use the Sec c 4 pollen allergen taught by Gavrovic et al. in the pharmaceutical compositions for treating type I hypersensitivity in a warm blooded animals sensitive to a pollen allergen comprising an effective amount of a pollen allergen to which said warm blooded animal is sensitive, a refined detoxified endotoxin selected from the group consisting of monophosphoryl lipid A and 3-deacylated monophosphoryl lipid A, and a pharmaceutically acceptable carrier taught by U.S. Patent 5,762,943 to treat type I hypersensitivity to Secale cereale pollen allergen Sec c 4.

11. Claims 26-28 appear to be in condition for allowance.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 16, 2010

/Nora M Rooney/

Primary Examiner, Art Unit 1644